mg of betamethasone. The dose may be repeated on 2 or 3 occasions, according to patient response. The sodium phosphate ester is also sometimes used with the acetate or dipropionale esters, which have a slower and more prolonged action. These suspensions may be given by intramuscular injection for a systemic effect, - or by intraarticular, soft-tissue, or intra lesional injection for local therapy. For doses used in children, see below.

Administration in children.

For parenteral use betamethasone sodium phosphate may be given intravenously by injection or infusion. It may be given to provide the

following doses equivalent to betamethasone:

infants aged up to 1 year: 1 mg

1 to 5 years: 2 mg

6 to 12 years: 4 mg

12 years and older: adult doses (see above) Doses may be repeated 3 or 4 times in 24 hours if necessary,

depending on the condition being treated and the clinical response.

Precautions:

Children (avoid prolonged use); adrenal suppression if used on a large area of the body or for a long time; particularly with an occlusive dressing or on broken skin; avoid use on the face for more than 7 days;

secondary infection requires treatment with an appropriate antimicrobial; may impair the ability to resist and counteract infections; diabetes mellitus; pregnancy

Adverse Effects

Exacerbation of local infection; local atrophic changes particularly on the face and in skinfolds; characterized by thinning of the dermis; depigmentation; dilatation of superficial blood vessels and formation of striae; perioral dermatitis; acne at site of application; suppression of the hypothalamic-pituitary-adrenal axis with prolonged or widespread use (particularly under occlusion); subcapsular cataract; osteoporosis; glaucoma; intracranial hypertension; psychic instability.

As for corticosteroids in general Betamethasone has little or no effect on sodium and water retention. When applied topically, particularly to large areas, when the skin is broken, or under occlusive dressings, or when given intra nasally, corticosteroids may be absorbed in sufficient amounts to cause systemic effects. Prolonged use of ophthalmic preparations containing corticosteroids has caused raised intra-ocular pressure and reduced visual function.

Drug Interactions

Corticosteroids may reduce the effects of anti cholinesterases in myasthenia gravis, cholecystographic x-ray media, salicylates and non-steroidal anti-inflammatory agents. The effect of corticosteroids may be reduced by phenytoin, phenobarbitone, ephedrine and rifampicin. 4 The dosage of concomitantly administered anti-coagulants may have to be altered (usually decreased). Oestrogens may potentiate the effects of glucocorticoids and dosage adjustments may be required if oestrogens are added to or withdrawn from a stable dosage regimen. Betamethasone is metabolised by CYP3A4 and co-administration with CYP3A inhibitors (e.g. ritonavir, cobicistat, itraconazole) is expected to increase the systemic concentration of betamethasone.

OVERDOSAGE:

Give supportive therapy as appropriate. Following chronic overdose, the possibility of adrenal suppression should be considered.

Treatment

There is no specific treatment for an overdose of betamethasone sodium phosphate. If overdose occurs, the patient is to be treated supportively with appropriate monitoring as necessary. Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

Pregnancy and Lactation

The use of corticosteroids during human pregnancy and lactation requires that the benefits be weighed against the possible risks associated with the product or with any alternative therapy.

Pregnancy There is insufficient evidence of safety in human pregnancy. Administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intrauterine growth retardation. The relevance of this finding to human beings has not been established, however, patients should avoid extensive use in pregnancy. Hypoadrenalism may occur in the neonate.

Lactation Corticosteroids are excreted in small amounts in breast milk and infants of mothers taking pharmacological doses of corticosteroids should be monitored carefully for signs of adrenal suppression

Storage: - Store Protected from light at a temperature not exceeding 30°C.

Improper Storage may deteriorate the product

Medicine: - Keep out of reach of children.

Presentation:- Betamethasone Injection IP 4.0 mg/ml in a 1ml ampoule.

Scan for Batch Certificate

Manufactured by:

AMERICAN REMEDIES
Care & Cure with Research
American Remedies Healthcare Pvt. Ltd.
(An ISO 9001-2015 Certified Company)

ICO: American Remedies LLC, DE, USA
Gala No. 105 to 111, 1st Flr., Bldg. No. E-15/A, Harihar Complex, Bhiwandi, Mumbai - 421302
At: Vill. Surajpur Nahan Road Paonta Sahib, Distt. Sirmour, Himachal Pradesh-173001
E-mail: info@americanremedies.in

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WHO GMP CERTIFIED

For the use of a Registered Medical Practitioner or a Hospital or Laboratory only.

℞ Betamethasone Injection IP

FOR IM OR IV USE ONLY

AMERICAN BETASTAL Injection

Composition:-

Each ml Contains: -

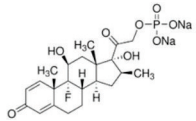
Betamethasone Sodium Phosphate Eq. to Betamethasone	IP	4 mg
Water for Injection	IP	q.s.

DESCRIPTION:-

Betamethasone Injection IP is a sterile aqueous Solution containing 4 mg per mL betamethasone, as betamethasone sodium phosphate, Betamethasone sodium phosphate is a white to practically white, odorless powder, and is hygroscopic. It is freely soluble in water and in methanol, but is practically insoluble in acetone and in chloroform

The formula for betamethasone sodium phosphate is $C_{22}H_{28}FNa_2O_8P$ and it has a molecular weight of 516.40. Chemically, it is 9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 21-(disodium phosphate).

The structrral formula of Betamethasone Sodium Phosphate is.



Betamethasone Sodium Phosphate

PHARMACOLOGY

PHARMACOKINETICS

Betamethasone Sodium Phosphate is a synthetic glucocorticoid used primarily for its anti-inflammatory and immunosuppressive properties. Understanding its pharmacokinetics is essential for optimizing therapeutic efficacy and minimizing adverse effects. The pharmacokinetic profile of Betamethasone Sodium Phosphate involves several key processes: absorption, distribution, metabolism, and excretion

Betamethasone Sodium Phosphate is typically administered via intravenous, intramuscular, When administered intravenously, absorption is immediate and complete, providing rapid onset of action. Oral administration results in variable absorption due to gastrointestinal factors, but generally, it is well-absorbed. The phosphate ester form enhances water solubility, facilitating its absorption and administration in injectable forms.

Betamethasone Sodium Phosphate is rapidly distributed throughout the body. It exhibits high affinity for plasma proteins, primarily albumin, which influences its free and bound fractions. The drug readily crosses cell membranes, including the blood-brain barrier, allowing it to exert effects in various tissues. The volume of distribution (Vd) varies depending on the route of administration and individual patient factors, typically ranging from 0.4 to 1.0 L/kg.

Betamethasone undergoes extensive hepatic metabolism primarily through reduction and conjugation processes. Cytochrome P450 enzymes, especially CYP3A4, play a significant role in its biotransformation. The active metabolite, Betamethasone itself, retains pharmacological activity, contributing to the drug's therapeutic effects. The metabolism rate can be influenced by genetic factors, liver function, and concomitant medications.

The metabolites of Betamethasone Sodium Phosphate are primarily excreted via the kidneys. Renal clearance depends on glomerular filtration and tubular secretion. The elimination half-life varies but generally ranges from 3 to 5 hours in healthy individuals. In cases of renal impairment, the clearance may be reduced, necessitating dosage adjustments to prevent accumulation and toxicity.

DOSAGE AND ADMINISTRATION

Betamethasone is a corticosteroid with mainly glucocorticoid activity; the anti-inflammatory activity of 750 micrograms of betamethasone is equivalent to about 5 mg of prednisolone. It has been used, either in the form of

the free alcohol or in one of the esterified forms, in the treatment of conditions for which corticosteroid therapy is

indicated. except adrenal-deficiency states for which hydrocortisone with supplementary fludrocortisone is preferred. Its virtual lack of miner alocorticoid properties makes betamethasone particularly suitable for treating

conditions in which water retention would be a disadvantage.

For parenteral use the sodium phosphate ester may be given intravenously by injection or infusion or intramuscularly by injection in doses equivalent to 4 to 20 mg of betamethasone. Doses may be repeated 3 or 4 times in 24 hours if necessary, depending on the condition being treated and the clinical response. It may also be given by local injection into soft tissues in doses equivalent to 4 to 8